



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,443	11/16/2001	Hyam I. Levitsky	213026	1421

23460 7590 04/10/2003

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,443

Applicant(s)

LEVITSKY ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-28, 40-47 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-28, 40-47 and 50-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on January 29, 2003 has been entered as paper No. 6. The Examiner assigned to your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Currently, claims 1-14, 17-28, 40-47, and 50-53 are pending and under examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the remarks will not be reiterated. The arguments in paper #6 would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION REQUIREMENT

Claims 1-14, 17-28, 40-47, and 50-53 stand rejected, and the rejection has been modified under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In paper No. 6, applicants argue, with regard to "universal bystander cell line naturally lacks MHC-I and MHC-II antigens", that applicants have taught that ANY human cell line that naturally lacks MHC-I and MHC-II antigens can be modified to express GM-CSF, and whether or not a given human cell line naturally lacks MHC-I and MHC-II antigens is readily ascertainable; that numerous examples of such cell lines were known in the art prior to the effective filing date, and submit references of Wang et al, Ferrone et al, and Kageshita et al as support for the broadly claimed cell lines.

The arguments and references have been fully considered but they are not persuasive as to support the full scope of the claimed invention for reasons of record and following.

The specification fails to define the term, "naturally", given the plain meaning of the term, it stands for, "by nature, inherently", "without a doubt", "Present or produced by nature" in a standard English dictionary. In view of the art of the immunology, it is well known that almost all nucleated cells naturally and constitutively express MHC-class I molecule, whereas dendritic cells, B-lymphocytes, and macrophages naturally express MHC-class II molecule (*Janeway Jr. et al*, Immunobiology, 2001). Accordingly, it appears only red blood cells that do not have nuclei fit the category of "a universal bystander cell line", because they would naturally lack MHC-I and MHC-II antigens. However, neither the art of record nor specification teaches a cell line of red blood cells. And since the red blood cell lacking a nucleus, it is unclear, if not unlikely, whether they could be modified to express an exogenous nucleic acid, and efficiently at levels >500-1000ng GM-CSF/106 cells/24 hours. Therefore, the specification fails to provide

Art Unit: 1632

sufficient description to convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In light of the teachings in the specification, the term "naturally" seems to encompass tumor cells that lost the capability of expressing MHC-I due to cancerous mutations. For instance, claim 2 recites a human cell line, lacking MHC-I and MHC-II antigens and further lacking B-lymphocyte markers, an EBV genome, EBV associated antigen, and receptors for EBV; and claim 3 recites a human cell line derived from a blast crisis of chronic myeloid leukemia. The specification discloses a lymphoblast cell line K562 that meets these limitations (Specification, page 7, lines 4-9). However, the specification fails to teach the genus of cell lines that meet the limitations of the claims beyond K562. In view of the art of record, *Klein et al* (Int J Cancer 1976:18:421-31, IDS/AV) teach that K562 line is exceptional to the majority of a large number of human lymphoblast cell lines possess B-lymphocyte markers, an EBV genome, EBV associated antigens, and receptors for EBV. Apparently, neither the art of record nor specification teaches the presence of the genus of cell lines that meet claim limitations. Thus, the circular teaching of "ANY human cell line that naturally lacks MHC-I and MHC-II antigens" is insufficient to convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants submitted new references as support for the broadly claimed cell lines, which are all drawn to melanoma cell lines. For example, *Wang et al* (J Clin Invest 1993;91:684-92) teach melanoma cells SK-MEL-33, which lost MHC-class I expression due to a mutation that leads to a reading frame shift in beta2-microglobulin mRNA.

Art Unit: 1632

Ferrone et al (Immunol Today 1995;16:487-94) teach that approximately 16% of primary, 58% of metastatic melanoma cells, and 10% melanoma cell lines lack or have reduced levels of class I expression. However, these disclosed cell lines are not "naturally" lack class I expression, rather, they lost the ability of expressing class I due to cancerous mutations. Further, *Ferrone et al* also teach that certain melanoma cells were unexpectedly found to express class II antigens, and refer to the teaching of *Winchester et al* (PNAS 1978 Dec;75:6235-9). *Winchester et al* report that widespread expression of Ia molecule (HLA-DR, belong to MHC-II) was found on malignant melanoma lines (last paragraph of left column, page 6235). Particularly of interest, they teach that MHC-II (Ia Ag) is expressed in 100% of SK-MEL-33 melanoma cells (table 1). Thus, the SK-MEL-33 cells taught by Wang et al do not meet claim limitation, because they do not lack the expression of MHC-II. In view of these teachings, the newly submitted publications do not appear to support the subject matter of the claimed invention, because they do not provide even one known human cell line that naturally lacks both MHC-I and MHC-II antigens. Therefore, neither the specification nor newly submitted art provide an adequate written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Revised Interim Guidelines (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol 66. No. 4, Friday, January 5, 2001) state "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT

Art Unit: 1632

WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (Column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (Column 2, page 71436). In the instant case, in view of the breadth of the claims, the disclosed K562 cell line alone is insufficient to support claims to the genus.

Moreover, an adequate written description for a genus of cell lines that naturally lack MHC-I and MHC-II antigens requires more than a mere statement that it is part of the invention and reference to a potential method for identifying such; what is required is a description of the cell lines themselves. It is not sufficient to define the genus solely by its principal biological characterization, i.e. **"ANY human cell line that naturally lacks MHC-I and MHC-II antigens"**, or "any human cell line lacking B-lymphocyte markers, an EBV genome and associated antigen, and receptors for EBV", because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any cell line with that biological characteristics. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all cell lines that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43

Art Unit: 1632

USPQ2d 1398 (CA FC, 1997)). The court has made it very clear "CONCEPTION OF CHEMICAL COMPOUND REQUIRES THAT INVENTOR BE ABLE TO DEFINE COMPOUND SO AS TO DISTINGUISH IT FROM OTHER MATERIALS, AND TO DESCRIBE HOW TO OBTAIN IT, RATHER THAN SIMPLY DEFINING IT SOLELY BY ITS PRINCIPAL BIOLOGICAL ACTIVITY". *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claims 26 and 27 require the use of a defined culture medium for culturing any cell line(s) encompassed by the claims, however, not a single "defined culture medium" is disclosed in the specification. Only a brief statement, "the culture medium preferably is defined, i.e., serum-free" (Specification, page 14, line 26). In stead of teaching what the claimed medium comprises, the specification only teaches what the medium does not comprise, thus, it appears that any medium that do not contain the animal serum would meet claim limitation. An adequate written description for a genus of culture medium used for making the universal GM-CSF-expressing bystander cell lines requires more than a mere statement that it is part of the invention and reference to what it does not have; what is required is a description of the components of the medium. With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, which provide the means for practicing the invention. Therefore, the specification fails to provide an adequate written description to the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Therefore, for reasons of record and those set forth above, the instant specification fails to meet the written description requirement set forth under 35 U.S.C. §112, 1st paragraph.

ENABLEMENT REQUIREMENT

Claims 1-14, 17-28, 40-47, and 50-53 stand rejected, and the rejection has been modified under 35 U.S.C. 112, first paragraph, as containing subsection matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As discussed in the previous Office action paper No. 4 and the immediate proceeding section, since the specification fails to provide adequate written description for the critical materials used in the methods, i.e. the genus of the universal bystander cell lines lacking both MHC-I and MHC-II, and the genus of cells further lacking B-lymphocyte markers, an EBV genome, EBV associated antigen, and I receptors for EBV, one skilled in the art could not envision what is encompassed by the claims, and have to go through a large scale screening for the existing large numbers of cell lines, or discovering new cell lines. Accordingly, the skilled artisan could not practice the invention without first carrying out undue experimentation.

Moreover, applicants rely on the melanoma cells in the newly submitted references as cell lines that meet claim limitation, however, the art of record teaches that growing melanoma cells require the presence of an animal serum (*Winchester et al*,

Art Unit: 1632

right column, page 6235), whereas the claims require a defined medium lacking serum. The specification fails to teach any defined medium, the type of cell lines that require a defined medium, or a defined medium for growing melanoma cells, thus, fails to provide sufficient guidance to enable the claimed invention commensurate with the scope of the claims.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 17-22, 26, 27, 40-47, and 50-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim recitation, "naturally". The specification fails to define the term, and it is unclear what kind of absence of MHC expression is considered "naturally". For example, whether the term encompasses a cancerous mutation. Thus, the metes and bounds of the claims are unclear.

Claim 2 is vague and indefinite because the use of multiple "and" in the phrase "characterized by the absence...", it is unclear whether all recited elements are required to be absent, thus, the metes and bounds of the claim is unclear.

Art Unit: 1632

The claims are vague and indefinite because of the claim recitation, "defined medium". The specification states "the culture medium preferably is defined, i.e., serum-free" (Specification, page 14, line 26). Apparently, the specification only defines what the medium does not comprise, it is unclear whether any medium that do not contain serum would meet claim limitation, thus, the metes and bounds of the claims are unclear.

Please note that the following rejections under **35 USC § 103** apply, based on the assumption that certain melanoma cell lines are embraced by the claimed universal bystander cell lines, i.e. they lack both MHC-I and MHC-II antigens, particularly in view of newly submitted evidence by *Ferrone et al* (Immunol Today 1995;16:487-94).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7, 17, 20, 22, 28, 40, 41, 44, 45, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dranoff et al* (US 5,637,483, IDS/AB), in view of *Ferrone et al* (Immunol Today 1995;16:487-94), and as evidenced by *Thomas et al* (Human Gene Ther 1998 Apr;9:835-43).

Claims 1, 5, 7 are drawn to a human cell line lacking MHC-I and MHC-II antigen and modified to express GM-CSF under the control of a CMV promoter, at about 500-1000 ng or greater GM-CSF/ 10^6 cells/24 hours. Claims 17 and 20 are drawn to a composition comprising the modified cells and a cancer antigen. Claims 22, 28, 40, 41, 44, 45, 50, and 52 are drawn to methods of making and using such cells and composition for cancer immune therapy, optionally, the composition is irradiated

Dranoff et al teach transfecting tumor cells, particularly B16 melanoma cells, with a retroviral vector encoding GM-CSF operably linked to a CMV promoter (column 3, lines 60-62, and example 1), wherein the expression levels for GM-CSF is 500 ng/ml/1.0 copy (table 1), wherein a titer of one copy per cell corresponds to a titer of approximately 10^6 infectious particles (column 13, lines 50-51), and the melanoma cells contain a cancer antigen. Further, because the present application uses the same type of vector as *Dranoff et al*, the transfected cells would produce 1000 ng or greater GM-CSF/ 10^6 cells/24 hours. *Dranoff et al* go on to teach irradiating modified tumor cells before vaccination (column 14, lines 19-21), and that the method could be used in general vaccination for other tumor cells and infectious diseases because co-administration of antigens, tumor cells or otherwise, with cytokines can confer long term specific systemic immunity in individuals receiving injections of antigen-containing cells

Art Unit: 1632

(column 3, lines 14-59). However, it is unclear whether the B16 melanoma cells used by *Dranoff et al* expressing MHC-I or MHC-II. Although not relied upon, it is noted that *Thomas et al* teach that B78H1, a variant of B16 melanoma lacks MHC-I expression (See "Tumor cell lines", page 836).

Ferrone et al teach that about 16% of primary, 58% of metastatic melanoma cells, and 10% melanoma cell lines lack expression of HLA-I (MHC-I) antigen and melanocytes normally do not express MHC-II, thus, certain melanoma cells would lack the expression of both antigens (table 1). *Ferrone et al* teach that the knowledge is clinically relevant because the melanoma cells are used as a therapeutic strategy in inducing immune response to melanoma and lacking MHC-I may contribute to tumor escape of immune surveillance (right column, page 684).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Dandroff et al*, by simply substituting the B16 melanoma cells with melanoma cells lacking both MHC-I and -II as taught by *Ferrone et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention by using different type of melanoma cells according to the type of melanoma the individual suffering, because it is known that lacking expression of MHCs may contribute to tumor escape, and GM-CSF modified melanoma cells could trigger or enhance antitumor immunity in the recipient. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Art Unit: 1632

Claims 1, 5, 7, 11, 17, 20, 22-24, 28, 40, 41, 44, 45, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dranoff et al* (US 5,637,483, IDS/AB), and *Ferrone et al* (Immunol Today 1995;16:487-94) as applied to claims 1, 5, 7, 17, 20, 22, 28, 40, 41, 44, 45, 50, and 52 above, and further in view of *Shepard et al* (US 6,348,352) or *Polack et al* (US 6,521,449).

Claims 11, 23, and 24 are drawn to hygromycin resistant gene and a culture medium comprising about 400 µg/ml or greater hygromycin for selection of modified cells. *Dranoff et al* use neomycin not hygromycin as the selection marker.

Shepard et al teach using hygromycin resistance gene in a genetic construct as a selection marker (table 2) and a culture medium comprising 400 µg/ml hygromycin (column 9, line 2). *Polack et al* teach that hygromycin resistance gene could be used as a selection marker for eukaryotic cells (column 3, lines 20-22) and a selection medium containing 400 µg/ml hygromycin (column 9, line 43).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Dandroff et al*, by simply substituting the neomycin resistance gene with the hygromycin resistance gene as taught by *Shepard et al* (US 6,348,352) or *Polack et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the method according to the cell types used or the gene of interest. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 17-28, 40-47, and 50-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the claims of the cited patent.

The claims of present application and the claims of the cited patent are each drawn to a universal bystander cell line which lacks MHC-I and MHC-II antigen, which is a human cell line, and which is modified to express GM-CSF at about 500 ng or greater GM-CSF/10⁶ cells/24 hours. The claims of present application and the cited patent are not patentably distinct from each other also because they are each drawn to a method of making a universal GM-CSF-expressing bystander cell line, and a method of using such cells for cancer immune therapy.

The product/processes of the present application and the cited patent differ one from the other in that the claims of the cited patent is drawn to a particular cell line k562

Art Unit: 1632

and the methods of making/using such, whereas instant claims are drawn to a genus of the modified universal bystander cell lines, the method of making such, and the method of using such for immune therapy. However, they encompass the claims of the cited patent.

Therefore, the claims as written are co-extensive.

Conclusion


No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).


Q. Janice Li
Patent Examiner
Art Unit 1632


April 7, 2003